MAY 1 6 2002

K013764

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Osteogenics Biomedical, Inc.
3234 - 64th Street
Lubbock, Texas 79413
(806) 792-2311

Contact Person: Chad Bartee

Date of Preparation: November 12, 2001

II. DEVICE NAME

Proprietary Name: Immix™
Common Name: Bone Graft Extender
Classification Name: Material, Polytetrafluoroethylene Vitreous Carbon for Maxillofacial Reconstruction

III. PREDICATE DEVICE

HTR Polymer, U. S. Surgical (K904111)

IV. DEVICE DESCRIPTION

Immix™ is a DL-polylactide resorbable polymer material intended for use by itself or in combination with other materials to create space for bone regeneration. The material is packaged individually in various amounts and supplied sterile.

V. INTENDED USE

As a spacemaking device used in guided bone regeneration. Treatment of bony defects, ridge maintenance, alveolar socket preservation or ridge augmentation.

VI. COMPARISON TO PREDICATE DEVICE

The Immix™ polymer material is similar in composition, and identical in function and intended use to legally marketed devices such as HTR Polymer, U. S. Surgical.

The results of performance and biocompatibility testing show that the Immix™ polymer material is safe and effective for its intended use and performs at least as well as legally marketed predicate devices, such as the HTR Polymer material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2002

Osteogenics BioMedical, Incorporated
C/O Richard A. Hamer
Richard Hamer Associates, Incorporated
6401 Meadows West Drive
Fort Worth, Texas 76132

Re: K013764
Trade/Device Name: Immix Bone Graft Extender
Regulation Number: 878.3500
Regulation Name: Polytetrafluoroethylene with Carbon Fibers Composite Implant Material
Regulatory Class: Unclassified
Product Code: LYC and KKY
Dated: February 21, 2001
Received: February 25, 2002

Dear Mr. Hamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K013764

Device Name: Immix™ Bone Graft Extender

Indications for Use:

As a spacemaking device used in cranio-facial guided bone regeneration. Treatment of bony defects, ridge maintenance, alveolar socket preservation or ridge augmentation. Not to be used in load-bearing areas.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013764